

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of)

COMMUNITY MEDICAL IMAGING, INC.,)
a corporation,)

and)

THOMAS E. MILLER, and)
RUDSEN M. BUESER, M.D.,)
individuals.)

FDA Docket: No.: 97H-0379

0901

CONSENT DECREE AND
ORDER FOR CIVIL MONEY PENALTY

Petitioner, the Center for Devices and Radiological Health, Food and Drug Administration (FDA), filed a Complaint seeking administrative civil money penalties against Community Medical Imaging, Inc. (CMI, Inc.), a corporation that owned and operated a mammography facility, and the two individuals most responsible for its operation, Thomas Miller, the President of CMI, Inc., and Rudsen Bueser, its Supervising Radiologist. The Complaint alleged that Respondents violated the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, which authorizes the imposition of civil money penalties against persons and facilities that provide screening and/or mammography services in a manner that violates the MQSA. More specifically, the Complaint alleged that Respondents violated 42 U.S.C. § 263b(b)(1) by conducting mammography without a certificate as defined by the MQSA. FDA sought civil money penalties against each Respondent pursuant to 42 U.S.C. § 263b(h)(2)(A), for failure to obtain a certificate, and 42 U.S.C. § 263b(h)(2)(C),

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for each mammography conducted on a patient while the facility did not have a certificate.

Each Respondent represents that the documents he(it) submitted in Respondents' Exhibits 15-32 completely and accurately reflect his(its) past and current financial condition and Miller and CMI, Inc. further represent that he(it) cannot afford to pay the \$80,000 penalty initially sought by FDA against each Respondent in this case.

Respondents have appeared and consented to the entry of this Decree without contest and Petitioner has consented to this Decree:

It is hereby ORDERED, ADJUDGED, and DECREED that:

1. FDA has subject matter jurisdiction, as delegated by the Secretary of Health and Human Services to the Commissioner of Food and Drugs, over this action and personal jurisdiction over the parties, pursuant to 42 U.S.C. § 263b. Pursuant to 42 U.S.C. § 263b(h)(3) and the implementing regulations, 21 C.F.R. Part 17, the authority to conduct an administrative civil penalty hearing and assess a civil penalty is vested in an administrative law judge, appointed in accordance with 5 U.S.C. § 3105.

2. Between September 1996 and March 1997, Respondents Miller and CMI, Inc. violated 42 U.S.C. § 263b(b)(1) of the MQSA by conducting mammography without a valid certificate and are liable for civil money penalties pursuant to 42 U.S.C. §§ 263b(h)(2)(A) & (C). No finding of liability has been made with respect to Dr. Bueser.

3. Dr. Bueser shall pay \$5,000 within 45 days from the date of this Decree to settle these proceedings. Respondents Miller and CMI, Inc. shall pay a civil penalty, pursuant to 42 U.S.C. § 263b(h), of \$25,000. Respondents Miller and CMI, Inc. are jointly and individually liable for the total amount of that civil penalty.

4. Respondents Miller and CMI, Inc. and each and all of their officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, family members, directors, corporations, subsidiaries, affiliates, and partnerships), are hereby prohibited from, directly or indirectly, owning or operating a facility, as defined in 42 U.S.C. § 263b(a)(3), that performs mammography for a period of five years from the date of this Decree, except that Miller shall be granted six months from the date of this Decree to sell or otherwise divest himself of any interest he may have in a facility. Miller shall, beginning on the one year anniversary from the date this Consent Decree is entered and continuing on each six month anniversary thereafter until five years from the date of this Decree, certify in writing that he has not during the preceding six months directly or indirectly owned or operated a facility, as defined in 42 U.S.C. § 263b(a)(3), that performs mammography. This certification shall be submitted to the District Director of the Chicago District Office, 300 S. Riverside Plaza, 5th Floor, Suite 550 South, Chicago, Il 60606.

5. Respondents waive any right to a hearing under 42 U.S.C. § 263b(h) and (i), and any other right they may have to contest or appeal the imposition or amount of the penalty.

6. Miller and CMI, Inc.'s civil penalty described in Paragraph 3 shall be paid by monthly payments of \$1041.67 over 24 months commencing August 15, 1998. All late payments are subject to an interest charge of 15% per annum compounded daily commencing on the date payment is due. In the event that Miller fails to make any of the payments specified in this Decree, FDA may at its option declare Miller to be in default, and the full remaining unpaid balance shall become immediately due and payable without demand or other formality, judicial or otherwise, of any kind, all of which are expressly waived by Miller and CMI, Inc. Interest on said amount shall accrue at the rate of 15% per annum compounded daily from the date of default on the full remaining unpaid balance. Upon declaration of default, FDA shall mail, by first class mail, a notice of said default addressed to Miller at his last known address.


7. If Respondents violate this Decree and Petitioner is required to take action to enforce the Decree, Respondents shall, in addition to other remedies, reimburse Petitioner for the costs related to bringing such enforcement proceedings.

8. Respondents shall bear their own costs, including attorney fees, for defending this action and for compliance with this Decree.

9. The Administrative Law Judge retains jurisdiction of this action for the purpose of modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this 13th day of August, 1998.


ADMINISTRATIVE LAW JUDGE

For Respondents:

COMMUNITY MEDICAL
IMAGING, INC. and
THOMAS E. MILLER

By: _____
THOMAS E. MILLER
President
CMI, Inc.
Date: _____

RUDBEN M. BUESER, M.D.


By: _____
RUDBEN M. BUESER, M.D.
Date: _____

COLLINS & COLLINS

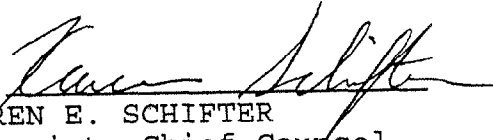
By: _____
MICHAEL R. COLLINS
Attorney for
Respondents
Date: _____

For Petitioner:

CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
UNITED STATES FOOD AND DRUG
ADMINISTRATION

By: 
D. BRUCE BURLINGTON, M.D.
Director
CDRH
Date: 8/5/98

MARGARET JANE PORTER
Chief Counsel

By: 
KAREN E. SCHIFTER
Associate Chief Counsel
Food and Drug Administration
Attorney for Petitioner
Date: 8-12-98

9. The Administrative Law Judge retains jurisdiction of this action for the purpose of modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this _____ day of _____, 1998.

ADMINISTRATIVE LAW JUDGE

For Respondents:

COMMUNITY MEDICAL
IMAGING, INC. and
THOMAS E. MILLER

By: Thomas E. Miller
THOMAS E. MILLER
President
CMI, Inc.
Date: 8/3/98

RUDSEN M. BUESER, M.D.

By: _____
RUDSEN M. BUESER, M.D.
Date: _____

COLLINS & COLLINS

By: Michael R. Collins
MICHAEL R. COLLINS
Attorney for
Respondents
Date: _____

For Petitioner:

CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
UNITED STATES FOOD AND DRUG
ADMINISTRATION

By: _____
D. BRUCE BURLINGTON, M.D.
Director
CDRH
Date: _____

MARGARET JANE PORTER
Chief Counsel

By: _____
KAREN E. SCHIFTER
Associate Chief Counsel
Food and Drug Administration
Attorney for Petitioner
Date: _____

9. The Administrative Law Judge retains jurisdiction of this action for the purpose of modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this _____ day of _____, 1998.

ADMINISTRATIVE LAW JUDGE

For Respondents:

COMMUNITY MEDICAL
IMAGING, INC. and
THOMAS E. MILLER

By: _____
THOMAS E. MILLER
President
CMI, Inc.
Date: _____

RUDBEN M. BUESER, M.D.

By: *Rudben Bueser*
RUDBEN M. BUESER, M.D.
Date: 8/3/98

COLLINS & COLLINS

By: *Michael R. Collins*
MICHAEL R. COLLINS
Attorney for
Respondents
Date: _____

For Petitioner:

CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
UNITED STATES FOOD AND DRUG
ADMINISTRATION

By: _____
D. BRUCE BURLINGTON, M.D.
Director
CDRH
Date: _____

MARGARET JANE PORTER
Chief Counsel

By: _____
KAREN E. SCHIFTER
Associate Chief Counsel
Food and Drug Administration
Attorney for Petitioner
Date: _____

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